DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2014

Oak Ridge Products LLC
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K141759
Trade/Device Name: Oak Ridge Products Multi-Purpose Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Sharps Container
Regulatory Class: II
Product Code: MMK
Dated: October 9, 2014
Received: October 10, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use

510(k) Number (if known): K141759

Device Name: Oak Ridge Products Multi-purpose Sharps Containers

Model Numbers:

Multi-purpose sharps containers							
Oak Ridge Part Number	**Product Description and closure type**	**Access opening size**	**Overall Size L x W x H**	**Weight (grams) empty**	**Total Capacity**	**Capacity at full line**	**Mounting**
0330-150S	Medium Red Sharps container – Sliding door	2.5 x 2.5 inches	12.5 x 6 x 13.5 inches	525 grams	2.9 gallons	2.4 gallons	Free Standing or Bracket
0330-150M	Medium Red Sharps container– Counter balanced door	8.5 x 1.75 inches	12.5 x 6 x 16.0 inches	586 grams	2.9 gallons	2.4 gallons	Free Standing or Bracket
0370-1500	Large Red Sharps container – with two hinged doors	13.75 x 4.75 inches (Major) 8.75 x 1.75 inches (Minor)	15.5 x 12 x 13.75 inches	1228 grams	7.6 gallons	6.1 gallons	Free Standing

Indications for Use:

Oak Ridge Products Sharps containers are a single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target population is for trained healthcare professionals.

The containers 0330-150S and 0370-1500 are intended to be used in areas where there is no unsupervised patient access.

The 0330-150M container with the counterbalanced closure is intended to be used in areas that have unsupervised patient access.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Summary Preparation Date: October 6th, 2014

1. Submitted By

Oak Ridge Products L.L.C.
4612 Century Court
McHenry, Illinois, 60050 USA
Establishment Registration #:1419823

2. Contact Information (Primary)

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3. Device identification:

Trade Name: Oak Ridge Products Multi-purpose Sharps Container
Common Name: Sharps Container
Product Code: MMK
Classification: Accessory to hypodermic single lumen needles
CFR Reference: 21 CFR 880.5570 – Class II
Classification Panel: General Hospital

4. Predicate devices:

Trade Name: Oak Ridge Products - Sharps Container
Common Name: Sharps Container
Product Code: MMK
Classification: Accessory to hypodermic single lumen needles
CFR Reference: 21 CFR 880.5570 – Class II
Classification Panel: General Hospital

Legally Marketed Equivalent Device:

Company	Product	510(k)#
Oak Ridge Products	1 quart Phlebotomy Sharps Container	K130281
Oak Ridge Products	2 Gallon Sharps Container	K130281

5. Product Description:

The Oak Ridge Products Sharps Containers are of injection molded polypropylene plastic, designed for a single-use by health care professionals. No part of the container is intended to come in contact with patients. The containers are designed to be puncture resistant, leak resistant on the sides and bottom, impact resistant, closable and stable. Large access openings allow for disposal of sharps with one hand use. The plastic used for the sharps containers are of a similar chemical formula as the comparable predicate devices and many of the sharps objects that will be placed within the container such as plastic syringe bodies. These containers are suitable for a terminal disposal by incineration and all materials used are fully consumable during incineration.

The Oak Ridge Products Sharps Containers are made of three parts (a base, a lid, and a closure) that form a single unit. The lid and closure come preassembled with the base not attached. Parts are nested to together to reduce storage and shipping requirements. The health care facility performs the final assembly on-site by snapping the lid to the base.

General Specifications:

Multi-purpose sharps containers							
Oak Ridge Part Number	**Product Description and closure type**	**Access opening size**	**Overall Size L x W x H**	**Weight (grams) empty**	**Total Capacity**	**Capacity at full line**	**Mounting**
0330-150S	Medium Red Sharps container – Sliding door	2.5 x 2.5 inches	12.5 x 6 x 13.5 inches	525 grams	2.9 gallons	2.4 gallons	Free Standing or Bracket
0330-150M	Medium Red Sharps container– Counter balanced door	8.5 x 1.75 inches	12.5 x 6 x 16.0 inches	586 grams	2.9 gallons	2.4 gallons	Free Standing or Bracket
0370-1500	Large Red Sharps container – with two hinged doors	13.75 x 4.75 inches (Major) 8.75 x 1.75 inches (Minor)	15.5 x 12 x 13.75 inches	1228 grams	7.6 gallons	6.1 gallons	Free Standing

The Medium capacity container is offered with two different models. The model 0330-150S has a sliding closure which when fully snapped locks the access opening for final disposal. This configuration is intended for OR areas where a large easy access is required for disposal of sharps objects. The model 0330-150M uses a counter balanced door that is suitable for use with unrestricted patient access. Both devices are free standing or can be wall mounted with a locking wall bracket PN 1030-9904.

The Large container lid design allows for use as a conventional sharps container or disposal of larger sharps. This is accomplished by two closures. The lid is design in two regions which are connected by a large flexible hinge. The lid regions and hinge are molded as a single component.

For use as a standard sharps collector: The entire lid is snapped onto the base. The small opening and closure are used. This provides a high capacity sharps collector for small to moderate sized sharps objects. When the container is full the small closure is closed by pressing down on the three snaps marked on the closure. Once snapped the container is ready for disposal.

For use as a large sharps collector: One half of the lid is snapped onto the base, the other half is folded over leaving the large opening. A small strap and hook which is molded as

part of the lid is used to keep the large closure in the open position. This allows one half of the lid to act as a large closure, allowing single hand disposal of large sharps objects. The flexible hinge area is covered on the underside of the lid by a guard that prevents sharps objects from penetrating the thinner hinge area of the lid. When the container is full, the strap is released. Both the large half lid and the small closure are snapped closed the container is ready for disposal.

Both the hinge guard and small aperture closer are installed at the time of manufacture and becomes integral to the lid assembly. The fastening method used is permanent and not removable by the user.

Lids and closures are uncolored translucent material allowing for a visual determination of fill level. The base is made from a high strength material to support the large capacity of the container. The recommended fill level is engraved onto the plastic and corresponds to the fill level line on the product identification label. Carrying handles are molded into the upper rim of the container allowing for fingers to be above the fill level.

The both the Oak Ridge Products Medium and Large Sharps Container conform to the recognized standard ASTM F2132-01(2008) for needle puncture resistance. These also meet or exceed the OSHA 1910.1030 recommendations for sharps containers.

6. Indications for Use:

Multi-purpose sharps containers							
Oak Ridge Part Number	**Product Description and closure type**	**Access opening size**	**Overall Size L x W x H**	**Weight (grams) empty**	**Total Capacity**	**Capacity at full line**	**Mounting**
0330-150S	Medium Red Sharps container – Sliding door	2.5 x 2.5 inches	12.5 x 6 x 13.5 inches	525 grams	2.9 gallons	2.4 gallons	Free Standing or Bracket
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Oak Ridge Products Sharps containers are a single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target population is for trained healthcare professionals.

The containers 0330-150S and 0370-1500 are intended to be used in areas where there is no unsupervised patient access.

The 0330-150M container with the counterbalanced closure is intended to be used in areas that have unsupervised patient access.

7. Comparison to Predicate Devices:

Manufacturer	**Oak Ridge Products** (New Devices)	**Oak Ridge Products** (Predicate Device)
Trade Name	Oak Ridge Products Sharps Containers	Oak Ridge Products Sharps Containers
510(k) number	K141759	K130281
Indication for use	Oak Ridge sharps containers are intended to be used for the safe disposal of hazardous sharps	Oak Ridge sharps containers are intended to be used for the safe disposal of hazardous sharps
Target Population	Healthcare professional	Healthcare professional
Where used	Healthcare facilities	Healthcare facilities
Material	Polypropylene	Polypropylene
Sharps access	Sharps inserted through the top	Sharps inserted through the top
Sharps closure	Closure feature is closed then locked in place for removal	Closure feature is closed then locked in place for removal
Impact resistance	Yes	Yes
Puncture resistance	Yes	Yes
Leak resistance	Yes	Yes
Single use	Yes	Yes
Non-sterile	Yes	Yes
Capable of maintaining a stable, upright position	Yes	Yes
No features to bend, break, or shear needle.	No Feature Present	No Feature Present
Reusable Sharps Containers	Same	Labeling is “Single Use Only”
Overfill Indication	Same	“Do Not Overfill” or “Fill to this Level Only” is Labeled or embossed on the container at the location of the full point. Labeling includes a “Fill Line”.
Clarity	Same	Each Collector has a minimum of one translucent component, either base or top.
Construction	Same	Injection Molded Containers, Lids and Closure
Unwinder	Feature present only on Large container	1 quart Phlebotomy containers have this feature

8. Substantial Equivalence Discussion of Similarities and Differences:

The Oak Ridge Products Multi-Purpose Sharps Containers are similar to the Oak Ridge Products Sharps Containers in:

- Intended use
- Target population
- Materials
- Design
- Performance testing

9. Intended use comparison:

The intended use of the new Oak Ridge Products Multi-Purpose Sharps Container is the same as the predicate device. Oak Ridge Products Sharp Containers are containers intended for the disposal of contaminated sharps waste in a healthcare facility.

10. Design and Material Comparison:

The design and functional characteristics of the Oak Ridge Products Sharps Containers and the predicate device are similar. The Oak Ridge Products Multi-Purpose Sharps Container parts are nestable and when assembled form a single unit. These units have features to prevent contact between user and the contents and are designed for a visual determination of the maximum capacity. None of the devices have features that bend, break, or shear needles. The devices are designed for a single use by a locking feature in the lid and closure or access door.

They are constructed of an injection molded polypropylene. Oak Ridge Products Sharps Containers are colored red with translucent lid that allows for a visual determination of content level.

11. Summary of Non-Clinical Performance Bench Testing:

11.1 Performance Standards:

The Recognition Number 6-215 identifies ASTM F2132-01 (reapproved 2008), "Standard Specifications for puncture Resistance of Materials Used for the Collection for Discarded Medical Needles and Other Sharps."

The Recognition Number 6-293 identifies ISO 23907 First Edition 2012-09-01, "Sharps injury protection - Requirements and test methods - Sharps containers"

The performance testing demonstrates compliance with the recognized consensus standards:

- ASTM F2132-01 (reapproved 2008), "Standard Specifications for puncture Resistance of Materials Used for the Collection for Discarded Medical Needles and Other Sharps."

- Applicable portions of ISO 23907 First Edition 2012-09-01, “Sharps injury protection - Requirements and test methods - Sharps containers”

In addition the relevant FDA guidance document, “Guidance on the Content and Format of Premarket Notification [510(k)] Submission for Sharps Collectors dated October 1993”, was used to identify applicable physical and mechanical features of the Oak Ridge Products multi-purpose sharps containers and the predicate device.

All applicable standards have been used to show that the Oak Ridge Products Medium and Large Sharps Container is substantially equivalent to the appropriately listed predicate device.

The performance testing summary demonstrates substantial equivalence between the Oak Ridge Products Medium and Large device and the predicate device. The Oak Ridge Products Medium and Large Sharps container has been tested by appropriate methods with respect to the relevant standards, FDA recognized ASTM standards F 2132-01, OSHA regulations 29 CFR Part 1910:1030 and ISO 23907:2012(e). No new issues of safety and effectiveness were raised with the testing performed, and the Oak Ridge Products Sharps containers are considered substantially equivalent to its predicate device.

11.2 Performance Testing (Bench) – Product Testing

The Oak Ridge Products Medium and Large Sharps Containers incorporate equivalent collector design features and performance characteristics.

The results of the product performance testing demonstrated equivalent performance to the predicate device performance and no new issues were raised.

Test Methods:

Puncture Resistance (Performed by an independent materials testing lab) – Passed
ASTM F 2132-01 (2008) “Standard Specification for the Puncture Resistance of Materials used in containers for the Discarded Medical Needles and Other Sharps”.

Leak Resistance of bottom and sides – Passed
Based on OSHA Specification 29CFR 1910:1030

Overfill detection and Capacity: – Passed

Needle unwinder and recapper: - only present on the large model - Passed

Impact resistance and safe handling – Passed
Based on ISO 23907:2012

Sharps access, closure and minimization of aerosolization: – Passed
Based on ISO 23907:2012

Stability: – Passed
Based on ISO 23907:2012

Mounting Brackets usability and stability: – Passed: Applies only to the Medium sharps container. The Large container is a free standing device.

Handle Strength: – Passed
Based on ISO 23907:2012

11.3 Performance test summary:

The performance testing summary demonstrates substantial equivalence between the Oak Ridge Products device and the predicate devices. The Oak Ridge Products Medium and Large Sharps containers have been tested by appropriate methods with respect to the relevant standards, FDA recognized ASTM standards F 2132-01, OSHA regulations 29 CFR Part 1910:1030 and ISO 23907:2012(e). No new issues of safety and effectiveness were raised with the testing performed, and the Oak Ridge Products Sharps containers are considered substantially equivalent to its predicate device.

12. Conclusion:

The Oak Ridge Products Medium and Large Sharps Containers introduces no new questions concerning the safety or effectiveness and proves to be substantially equivalent to the respective predicate sharps collectors.